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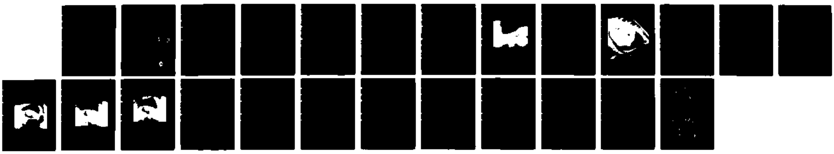

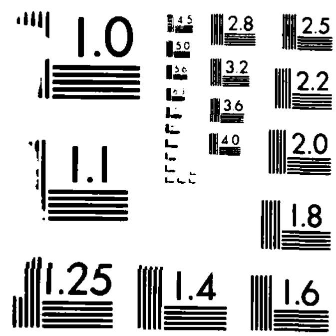
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SOFT CONTACT LENS WEAR DURING $+G_Z$ ACCELERATION

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NOTICES

This final report was submitted by personnel of the Ophthalmology Branch, Clinical Sciences Division, USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, Brooks Air Force Base, Texas, under job order 2729-06-02.

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The voluntary informed consent of the subjects used in this research was obtained in accordance with AFR 169-3.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

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The effects of $+G_z$ on soft contact lens wear are reported here. Human centrifuge rides up to +8 G_z were accomplished on 11 subjects. Six myopic subjects were tested with low-, medium-, and high-water-content spherical soft lenses. Two astigmatic subjects were tested with various designs of toric soft lenses. In addition, the contact lens subjects were tested with spectacles for comparison. Three emmetropic subjects served as controls. Video photography was used to monitor lens position during the centrifuge rides; and visual acuity was checked at +1, +2, +4, +6 and +8 G_z with a reduced Snellen eye chart. Each lens type and control run was evaluated in straight-ahead, lateral, and vertical gaze. No significant decentration was noted for any of the lens types tested up to the maximum level of +8 G_z. Visual acuity was reduced at the higher $+G_z$ levels for contact lenses, and spectacle trials, and with the emmetropic controls--all to similar levels. Contact lens did not produce any corneal insult due to the $+G_z$ exposure.

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SOFT CONTACT LENS WEAR DURING $+G_z$ ACCELERATION

INTRODUCTION

Contact lens use in aviation has long been a subject of controversy. Of great concern in military aviation is the potential for lens decentration and dislodgement during periods of acceleration which generate high gravitational forces. This problem is of special concern for increased gravitational forces tangential to the cornea, such as along the z-axis ($+G_z$) (Fig. 1). The reason

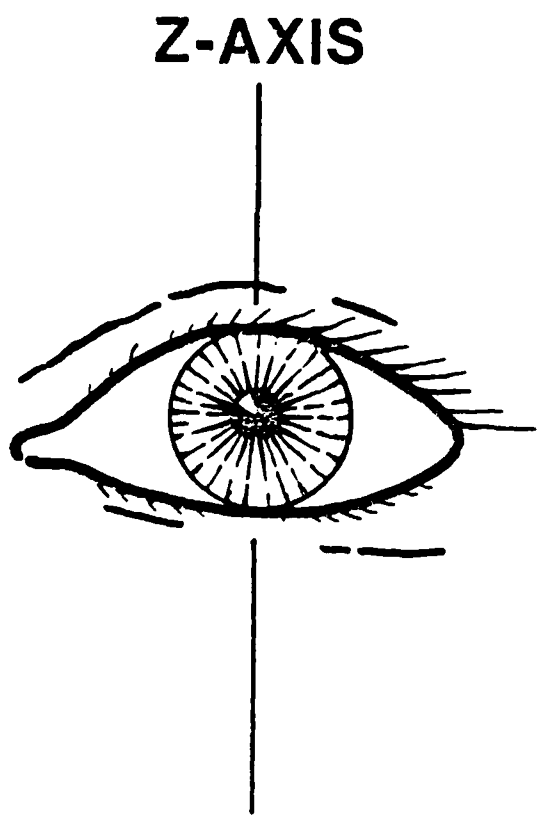

Figure 1. The direction of $+G_z$ force in relation to the eye.

for this concern was demonstrated by Tredici and Welsh, when they found significant lens decentration with hard contact lenses under six times the normal force of gravity (+6 G_z)(1). The lens decentration they found was great enough to severely reduce vision, since the lens margins impinged well into the pupillary area (Fig. 2).

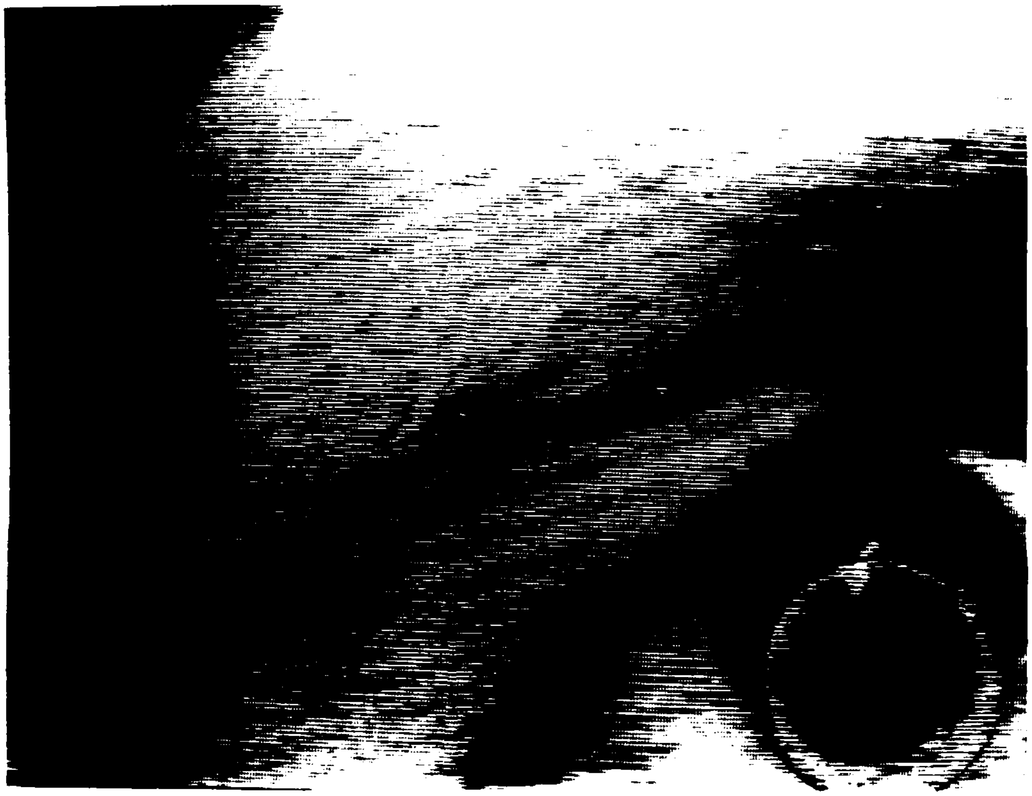

Figure 2. A centrifuge ride at +6 G_z, showing a hard contact lens decentered inferiorly. (Photograph from a video tape)

The fitting characteristics of soft contact lenses are distinctively different from those of hard contact lenses. Hard lenses are fitted within the corneal diameter, with a spherical back curve that approximates the central corneal curvature. Lens centration is achieved by tear fluid forces, by

the flattening of the peripheral cornea, and by the superior eyelid's holding the lens in place. On the other hand, soft contact lenses are flexible and larger than the corneal diameter. They bridge the peripheral cornea and limbus and rest on the corneal apex and sclera. Since the sclera is considerably flatter than the cornea, soft lenses center well and move very little. Because of these different fitting characteristics, $+G_z$ acceleration will predictably have different effects on these two lens designs.

In 1975, Polishuk and Raz fitted 10 Israeli Air Force pilots with soft contact lenses and reported no subsequent complaints from the pilots undergoing aircraft maneuvers up to $+6\ G_z$ (2). Similarly, Nilsson and Rengstorff reported the absence of lens-related symptoms, up to $+6\ G_z$, in four Royal Swedish Air Force jet pilots wearing extended-wear soft lenses (3). On a human centrifuge, Forgie and Meek tested soft contact lenses up to $+6\ G_z$, and found small amounts of decentration which they believed would not interfere with vision (4). Also on a human centrifuge, Brennan and Girvin tested soft lenses to $+6\ G_z$, and included visual acuity measurements in their evaluations (5). These authors found a maximum lens decentration of 2 mm at $+6\ G_z$ and, in visual acuity, minor reductions which they attributed to retinal ischemia.

The objective of our present study was to determine the centration characteristics and visual performance of soft contact lenses up to $+8\ G_z$ on a human centrifuge. These parameters were evaluated in both the static straight-ahead gaze and in the kinetic states of lateral and vertical (up) gaze.

METHODS

A total of 11 subjects, from whom informed consent had been obtained, participated in this study. All subjects were well-trained and experienced centrifuge riders. All were free of ocular disease and had ocular parameters within normal limits. The soft lenses were fitted by accepted standards, and a minimum of one month's successful contact lens wear was required before centrifuge testing.

Testing of increased gravitational forces along the z-axis ($+G_z$) was accomplished on the USAF School of Aerospace Medicine human centrifuge. A video camera, equipped with a zoom lens, was used to monitor lens position during the centrifuge rides; and, to render the contact lenses more visible on video tapes, the lenses were marked in the periphery with a Sanford's Sharpie 3000 fine point marker (Fig. 3) (6).

Visual acuity measurements were taken with reduced Snellen charts placed in positions that required lateral (approximately 75°), vertical (approximately 25°), and straight-ahead gaze (Fig. 4). Visual acuity was measured binocularly (except for one unilateral lens wearer), and was checked at $+1\ G_z$ (baseline), $+2\ G_z$, $+4\ G_z$, $+6\ G_z$, and $+8\ G_z$ levels. A slit lamp examination was performed before and immediately after each centrifuge trial.

Figure 3. Peripheral contact lens markings for higher visibility during centrifuge video taping.

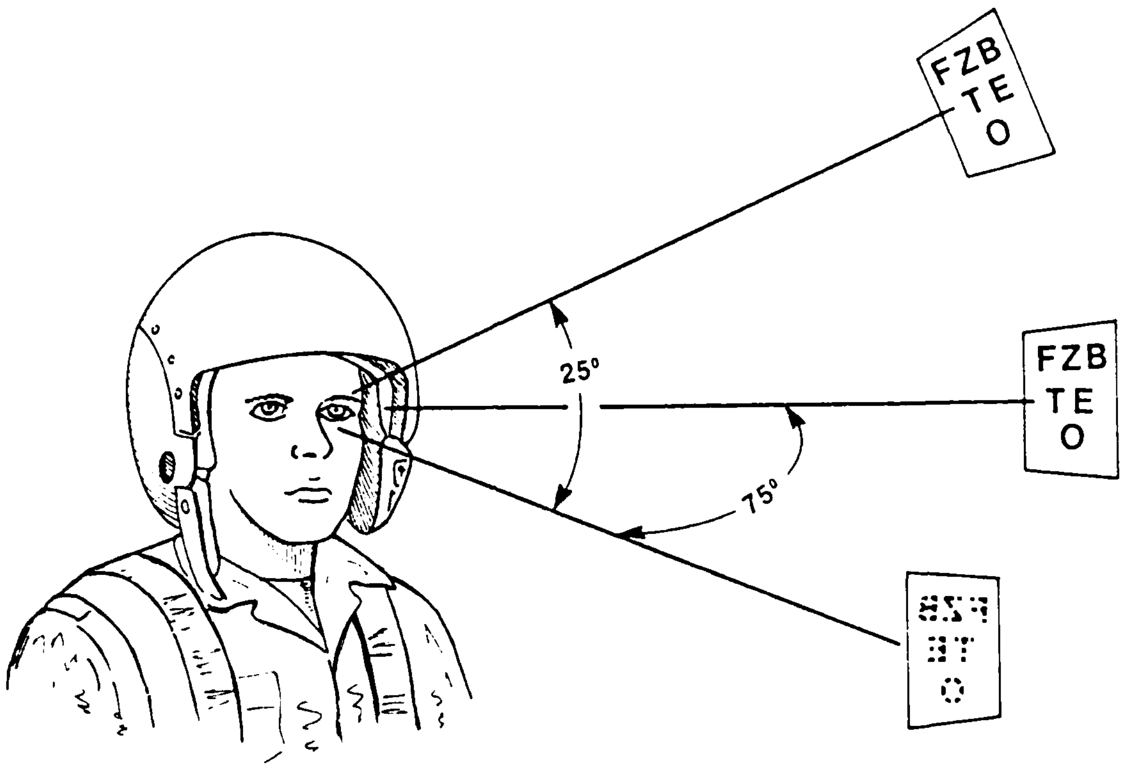

Figure 4. The different directions of gaze tested on the centrifuge.

For each lens type, the centrifuge testing consisted of four rides. On the first ride, visual acuity measurements were taken in straight-ahead gaze. On the second ride, visual acuity was measured in lateral gaze, followed by straight-ahead gaze at each $+G_z$ level; and, similarly, on the third ride, visual acuity was measured in vertical gaze, followed by straight-ahead gaze.

The fourth ride consisted of fluctuating $+G_z$ levels to simulate aircraft combat maneuvers. The study protocol for centrifuge testing of each lens type is summarized in Table 1.

Initial Trials

Initially, three contact lens subjects and one emmetropic control were evaluated at levels up to $+6\ G_z$ and were not tested in the air combat maneuvers. The lens types tested in these trials are listed in Table 2.

Spherical Lenses

Two subjects wearing spherical soft lenses were tested up to $+8\ G_z$. Subject 7 was tested with three designs of spherical lenses, and Subject 8 with two designs; both were tested with spectacles (Table 3).

Emmetropic Controls

Two emmetropes serving as controls were tested under the complete study protocol (Table 1) and are listed in Table 3.

Toric Lenses

Along with spectacles, toric lens designs (for the correction of astigmatism) were evaluated up to $+8\ G_z$ on three subjects. Toric soft lenses are manufactured with the cylinder on either the front or back of the lens, and with a prism ballast in the inferior portion of the lens for stabilization. This additional weight, located right along the direction of force of $+G_z$, should predictably render this soft lens design more susceptible to decentration off the cornea. The various designs of toric lenses tested are listed in Table 4.

RESULTS

Initial Trials

The results of visual acuity measurements from 30 preliminary trials tested to $+6\ G_z$ are shown in Table 5. The visual acuities reported in Table 5 are from the ride showing the greatest change; no visual acuity changes were detected at $+2\ G_z$ or $+4\ G_z$ in any trial. Spectacle wear was not evaluated in these trials, but one emmetropic control was tested and is listed in Table 5 for comparison. For all four of the subjects, visual acuity remained 20/20 or

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EDITOR'S NOTE: For the convenience of the reader, all of the tables have been grouped at the close of this Report.

better at all $+G_z$ levels, although in Subjects 1 and 3, visual acuity did drop from 20/15 to 20/20 at +6 G_z in lateral or vertical gaze.

The fact that lens centration remained good during all of the rides is consistent with the visual acuity results. Maximum lens decentration was estimated from the video tapes to be 1.0 mm in straight-ahead and lateral gaze at +6 G_z and was slightly greater in vertical gaze (1.5 mm). Post-ride slit lamp examinations did not reveal any adverse physiologic responses.

Spherical Lenses

The visual acuity results with the various spherical lens types tested are listed in Table 6. Also shown in Table 6 are the spectacle visual acuities for each subject. Visual acuity did decrease from baseline levels (+1 G_z) at both +6 G_z and +8 G_z, and this decrease occurred for all contact lens types and spectacles. The visual acuity levels measured in lateral and vertical gaze showed slightly greater changes than straight-ahead levels. The visual acuity results from the air combat maneuver ride were similar to the corresponding $+G_z$ levels of the straight-ahead gaze trials (Ride 1).

Similar to the preliminary trials, the absence of major visual acuity changes with the spherical lenses predicted the absence of significant lens decentration. This finding was confirmed on the video tapes, and maximum lens decentration was estimated to be less than 2 mm in vertical gaze and slightly less in straight-ahead and lateral gaze. The absence of significant lens decentration is depicted in Figures 5, 6, and 7, which are photographs from a video tape of Subject 7 in vertical gaze at +4 G_z, +6 G_z and +8 G_z. (Note: Maximum decentration cannot be estimated from these still photographs, because they were taken at various times after a blink.) No adverse physiologic responses were detected in post-ride slit lamp examinations.

Emmetropic Controls

The visual acuity results from the two control subjects tested up to +8 G_z are shown in Table 7. The visual acuities at +2 G_z and +4 G_z remained the same as the baseline values, but were reduced at +6 G_z and +8 G_z to levls similar to those found with the spherical lenses.

Toric Lenses

The visual acuity results from the toric soft lenses at +1 G_z, +6 G_z and +8 G_z are listed in Table 8. Also listed in Table 8 are the spectacle visual acuity results of the toric lens subjects. As with the spherical lenses, visual acuity was unchanged at +2 G_z and +4 G_z, but decreased at +6 G_z and +8 G_z, and again for both toric contact lenses and spectacles. The visual acuity levels for the subjects wearing toric lenses were slightly more reduced than with the spherical lens subjects, but the reduced levels for toric lens subjects were still not significantly different from their spectacle acuities. The air combat maneuver visual acuity results were similar to the results of the straight-ahead gaze visual acuities (Ride 1).

Decentration for the toric lenses was slightly greater than with the spherical lenses. Maximum lens decentration was estimated to be 2.0 mm, and was again greatest in vertical gaze. Post-flight slit lamp examinations were unremarkable.

Figure 5. Subject 7, wearing a 42.5% H_2O lens in vertical gaze at +4 G_z. (Photograph from a video tape)

Figure 6. Subject 7, wearing a 42.5% H_2O lens in vertical gaze at +6 G_z. (Photograph from a video tape)

Figure 7. Subject 7, wearing a 42.5% H_2O lens in vertical gaze at +8 G_z. (Photograph from a video tape)

DISCUSSION

High gravitational forces along the z-axis ($+G_z$) pose a significant hazard to hard contact lens wear due to the risk of decentration and dislodgement from the eye (1). This hazard may be lessened by the use of large lens diameters, aspheric base curves for better corneal alignment, and the new gas-permeable materials which make larger lens diameters more physiologically acceptable and offer lower specific gravities than polymethylmethacrylate (PMMA) hard lenses.

Soft contact lenses have overall diameters in the range of 13.5-15.0 mm, and thus completely cover the cornea with an additional 2- to 3-mm limbal flange. Because of this large overall lens size, the lenses can be manufactured with large optical zones. Consequently, small soft lens decentrations may occur (for example, the 2 mm found in this study) without significant effects to vision.

Soft toric lenses are commonly manufactured with a prism ballast to stabilize the lens in the proper position for the cylinder axis. The prism ballast adds extra weight to the inferior portion of the lens and, as a result of gravity and lid forces, stabilizes the desired cylinder axis location of the lens on the eye. This additional weight should render these lenses more susceptible to decentration under high $+G_z$ levels. The premise held true in this study, since the toric lenses showed the greater amounts of decentration. Also, the toric visual acuities were slightly more reduced than those found with spherical lenses. A plausible cause for this visual acuity difference could be a result of small toric lens rotations under $+G_z$. A prism ballast toric generally fits on the eye with a 5- to 10-degree rotation of the 6 o'clock meridian (prism ballast location) (7). Under the force of $+G_z$, this meridian may have been rotated toward the vertical, thus changing the desired location of the cylinder axis. Although lens rotations were not evident on the video tapes, a small change in cylinder axis location would change the effective diopteric power of the eye-lens system, and may account for this visual acuity difference (8).

In this study, visual acuity reductions occurred consistently at +8 G_z. These reductions occurred with both spectacles and contact lenses, as well as with the emmetropic controls, all to similar levels. This finding suggests an etiology other than the optical correction as the responsible site for the reductions. The most logical explanation is as a consequence of retinal ischemia (5, 9, 10). Four subjects reported visual field loss (greyout) at +8 G_z in a number of trials, thus supporting the retinal ischemia theory. Also, a potential contributing factor to the visual acuity reductions could be the drooping of the superior eyelashes into the pupillary axis--a factor which was consistently noted on the video.

In contrast to hard contact lenses, soft contact lenses performed quite well under increased gravitational forces. Similar to previous reports (2-5) of soft contact lens wear under gravitational forces up to +6 G_z, this study found no significant lens decentration up to the maximum tested level of +8 G_z. Also, visual acuities with soft lenses worn at +8 G_z were similar to those found with spectacle wear and with emmetropic controls under the same conditions. This favorable performance of soft contact lenses in centrifuge

testing to +8 G_z indicates that their wear should not be prohibited in aviation on the basis of $+G_z$ exposure.

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TABLES 1 - 8

TABLE 1. STUDY PROTOCOL FOR CENTRIFUGE TESTING OF LENS TYPES

Ride 1	Ride 2	Ride 3	Ride 4
+1 G_z, st[a]	+1 G_z, st, lt[b]	+1 G_z, st, up[c]	+1 G_z, st
+2 G_z, st	+2 G_z, st, lt	+2 G_z, st, up	+3 G_z, st
+4 G_z, st	+4 G_z, st, lt	+4 G_z, st, up	+7 G_z, st
+6 G_z, st	+6 G_z, st, lt	+6 G_z, st, up	+4.4 G_z, st
+8 G_z, st	+8 G_z, st, lt	+8 G_z, st, up	+3 G_z, st
+1 G_z, st	+1 G_z, st, lt	+1 G_z, st, up	+5 G_z, st
			+4 G_z, st
			+7 G_z, st
			+3 G_z, st
			+6 G_z, st
			+1 G_z, st

[a]st = straight-ahead gaze visual acuity measurement
[b]lt = lateral gaze (75 deg) visual acuity measurement
[c]up = vertical gaze (25 deg) visual acuity measurement

TABLE 2. INITIAL TRIALS OF LENS TYPES TESTED

Subject		Lens types	Power (D)
1	OD	Polymacon 38.6% H_2O	-4.25
	OS	Polymacon 38.6% H_2O	-3.75
2	OD	Phemfilcon 30% H_2O	-2.25
	OS	Bufilcon A 55% H_2O	-2.25
3	OD	Bufilcon A 45% H_2O	-1.50
	OS	Bufilcon A 45% H_2O	-2.00
4		Control	Emmetrope

TABLE 3. SPHERICAL LENSES TESTED UP TO +8 G_z

Subject		Lens types	Power (D)
5		Control	Emmetrope
6		Control	Emmetrope
7	OD	Tetrafilcon A 42.5% H_2O	-1.50
	OS	Tetrafilcon A 42.5% H_2O	-1.50
	OD	Perfilcon A 71% H_2O	-1.50
	OS	Perfilcon A 71% H_2O	-1.50
	OD	Phemfilcon 30% H_2O	-1.50
	OS	Phemfilcon 30% H_2O	-1.50
8	OD	Tetrafilcon A 42.5% H_2O	-1.50
	OS	Tetrafilcon A 42.5% H_2O	-1.50
	OD	Polymacon 38.6%	-1.50
	OS	Polymacon 38.6%	-1.50

TABLE 4. VARIOUS DESIGNS OF TORIC LENSES TESTED

Subject		Lens types	Prism diopters
9	OD	Phemfilcon A 30% H_2O	0.75 truncated
	OS	Phemfilcon A 30% H_2O	0.75 truncated
	OD	Bufilcon A 45% H_2O	1.00
	OS	Bufilcon A 45% H_2O	1.00
10	OD	None	
	OS	Hefilcon B 45% H_2O	1.00
11	OD	Bufilcon A 45% H_2O	1.00
	OS	Bufilcon A 45% H_2O	1.00
	OD	Hefilcon B 45%	1.00
	OS	Hefilcon B 45%	1.00

TABLE 5. VISUAL ACUITY RESULTS FROM 30 INITIAL TRIALS

Subject		Lens	No. of trials[a]	Visual acuity[b] +1 G_z	+4 G_z	+6 G_z
1	OD	38.6% H_2O	8 st	20/17	20/17	20/17
	OS	38.6% H_2O	1 lt	20/15	20/15	20/15
			1 up	20/15	20/15	20/20
2	OD	30% H_2O	2 st	20/15	20/15	20/15
	OS	55% H_2O	1 lt	20/15	20/15	20/15
			1 up	20/15	20/15	20/15
3	OD	45% H_2O	6 st	20/17	20/17	20/17
	OS	45% H_2O	3 lt	20/15	20/15	20/20
			3 up	20/15	20/15	20/20
4		Emmetrope	2 st	20/17	20/17	20/17
			1 lt	20/15	20/15	20/15
			1 up	20/15	20/15	20/15

[a]st = straight-ahead gaze; lt = lateral gaze (75 deg); up = vertical gaze (25 deg)

[b]Visual acuities reported are from the trial showing the greatest change. No visual acuity changes were detected at +2 G_z or +4 G_z.

TABLE 6. VISUAL ACUITY RESULTS--SPHERICAL LENSES

Subject		Lens	No. of trials[a]	Visual acuity[b] +1 G_z	+6 G_z	+8 G_z
7	OD	42.5% H_2O	2 st	20/17	20/17	20/20
	OS	42.5% H_2O	2 lt	20/20	20/20	20/20
			2 up	20/20	20/20	20/25
	OD	71% H_2O	2 st	20/17	20/20	20/30
	OS	71% H_2O	2 lt	20/15	20/20	20/30
			2 up	20/15	20/15	20/20
	OD	30% H_2O	2 st	20/17	20/17	20/17
	OS	30% H_2O	2 lt	20/15	20/15	20/20
			2 up	20/15	20/15	20/15
	OD	spectacles	2 st	20/17	20/17	20/20
			2 lt	20/20	20/20	20/30
			2 up	20/15	20/15	20/20
8	OD	42.5% H_2O	2 st	20/15	20/17	20/30
	OS	42.5% H_2O	2 lt	20/15	20/20	greyout
			2 up	20/12	20/15	greyout
	OD	38.6% H_2O	2 st	20/15	20/17	20/20
	OS	38.6% H_2O	2 lt	20/20	20/30	greyout
			2 up	20/12	20/15	20/20
	OD	spectacles	2 st	20/15	20/17	20/20
	OS		2 lt	20/20	20/40	greyout
			2 up	20/12	20/20	greyout

[a] st = straight-ahead gaze; lt = lateral gaze (75 deg); up = vertical gaze (25 deg)

[b] Visual acuities reported are from the trial showing the greatest change. No visual acuity changes were detected at +2 G_z or +4 G_z.

TABLE 7. VISUAL ACUITY RESULTS--CONTROL SUBJECTS

Subject	Lens	No. of trials[a]	Visual acuity[b] +1 G_z	+6 G_z	+8 G_z
5	Emmetrope	2 st	20/17	20/20	20/20
		2 lt	20/17	20/40	greyout
		2 up	20/17	20/17	20/20
6	Emmetrope	2 st	20/17	20/20	20/30
		2 lt	20/17	20/30	greyout
		2 up	20/17	20/17	20/30

[a,b] Information is as stated for Table 6.

TABLE 8. VISUAL ACUITY RESULTS--TORIC LENSES

Subject		Lens	No. of trials[a]	Visual acuity[b] +1 G_z	+6 G_z	+8 G_z
9	OD	45% H_2O	1 st	20/17	20/20	greyout
	OS	45% H_2O	2 lt	20/20	20/30	greyout
			2 up	20/15	20/15	greyout
	OD	30% H_2O	2 lt	20/20	20/20	greyout
	OS	30% H_2O	2 up	20/15	20/15	greyout
	OD	spectacles	1 lt	20/20	20/30	greyout
	OS		1 up	20/20	20/30	greyout
10	OD	none	2 st	20/17	20/20	20/30
	OS	45% H_2O	2 lt	20/20	20/40	20/40
			2 up	20/15	20/25	20/30
	OD	none	2 st	20/17	20/17	20/17
	OS	45% H_2O	2 lt	20/20	20/30	20/30
			2 up	20/20	20/20	20/30
	OD	spectacles	2 st	20/17	20/17	20/20
	OS		2 lt	20/15	20/15	20/20
			2 up	20/17	20/17	20/17
11	OD	45% H_2O	2 st	20/17	20/20	20/20
	OS	45% H_2O	2 lt	20/15	20/30	20/30
			2 up	20/15	20/15	20/20
	OD	45% H_2O	2 st	20/20	20/20	20/30
	OS	45% H_2O	2 lt	20/30	20/40	20/40
			2 up	20/20	20/20	20/20
	OD	spectacles	2 st	20/17	20/20	20/20
	OS		2 lt	20/20	20/30	20/40
			2 up	20/17	20/17	20/20

[a]st = straight-ahead gaze; lt = lateral gaze (75 deg); up = vertical gaze (25 deg)

[b]Visual acuities reported are from the trial showing the greatest change. No visual acuity changes were detected at +2 G_z or +4 G_z.

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